

REMARKS

Reconsideration of this application is respectfully requested. A three-month extension of time for responding to the outstanding Office Action of April 27, 2004 in this application is respectfully requested.

Claims 1, 6-19, 20-34, 48-51, 54, 61-67, 71-83, 93-99, 249, 250, 254 and 255 are pending in the application. It should be noted that the Examiner overlooked the pendency of claim 54 in her statement of the claims pending in the application in the Office Action Summary included with the outstanding Office Action. Upon entry of this Amendment, claims 1, 7, 9, 13, 16-19, 21, 226, 249 and 254 will be amended.

In the first full paragraph appearing on page 3 of the application and beginning on line 7, the term "cardia sphincter" has been replaced by the term "anal sphincter" to correct a typographical error. As stated on the first page of the present application, the present invention relates to an intestine dysfunction treatment apparatus. The intestine dysfunction may involve the disability of controlling the muscle that contracts the bowels, colon or rectum to provide transportation of the content thereof. The application also notes that the intestine dysfunction may involve anal incontinence, *i.e.*, the disability to close the anal sphincter. The definition of a cardiac sphincter, as defined by the Merriam Webster Medical Dictionary, is a somewhat thickened muscular ring surrounding the opening between the esophagus and the stomach. An excerpt from the IntelliHealth: Merriam-Webster Medical Dictionary website with this definition is attached for the

FORSELL
Serial No. 09/893,510

Examiner's consideration. As such, it is believed that one skilled in the art would appreciate that the term "cardiac sphincter" was improperly included in the application, and, as such, that the noted amendment to the application specification does not constitute the addition of new matter to this application.

In the outstanding Office Action, the Examiner stated that claims 100-248 and 251-253 have been withdrawn from consideration as being directed to non-elected species. Without specifically acquiescing in the Examiner's contentions, and to advance the prosecution of this application, applicant notes that, given the withdrawal of such claims from consideration, no further comment regarding such withdrawn claims will be made in this Amendment; except that Applicant proposes to amend claim 226 in response to the Examiner's question regarding the dependency of such claim to clarify its dependency as being from claim 224. Although noted as being "withdrawn", claim 226 is also noted as being "currently amended" to reflect this change.

In the outstanding Office Action, the Examiner also stated that the Action was "Final". On June 4, 2004, the undersigned had a telephonic interview with the Examiner, during which the undersigned explained to the Examiner his belief that the final rejection was premature based on the indication in the Office Action of May 29, 2003 that objected-to claim 5 would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. In the Amendment dated October 29, 2003, this amendment was made by including all of the limitations of claim 5

FORSELL
Serial No. 09/893,510

and intervening claims 2, 3, and 4 (all of which depended either directly or indirectly from claim 1) in amended claim 1 and canceling such dependent claims upon such amendment of claim 1. In this regard, a review of claim 1 reveals that the limitations of claim 3 appeared in the next to last paragraph of claim 1, and the limitations of claims 2, 4 and 5 appear in the last paragraph of claim 1, as claim 1 stood at the time of entry of the rejections in the Office Action of April 27, 2004. In the Interview Summary form issued by the Examiner for the June 4, 2004 telephonic interview, the Examiner acknowledged that the final rejection appeared to be improper. A copy of the Interview Summary form is submitted with this Amendment for the Examiner's convenience.

The Examiner also objected to independent claim 249 and its dependent claim 250 because the word "feces" is, according to the Examiner, misspelled as "faeces" in line 6 of claim 249. Although "faeces" is a recognized spelling alternative to the word "feces", claim 249 has been amended to change the spelling of the word "faeces" to "feces". Claims 13 and 16 have also been amended. Accordingly, the Examiner's objection to claims 249 and 250 should be withdrawn.

In the outstanding Office Action, the Examiner also rejected claims 1, 6-17, 20-34, 49-51, 61-67, 71, 72, 75, 80-83, 93, 95-99, 249, and 250 under 35 U.S.C. §102(e) as being anticipated by Bardy (USP 6,238,423), claims 18, 19, 254 and 255 under 35 U.S.C. §103(a) as being unpatentable over Bardy alone, and claims 48, 73, 74, 76-79, and 94

under §103(a) as being unpatentable over Bardy in view of Rosar (USP 6,223,083). The Examiner's rejections are respectfully traversed.

In the present application, independent claim 1 describes an intestine dysfunction treatment apparatus, which includes, *inter alia*, "a control device controllable from outside the patient's body to control the internal electric source of energy to release electric energy for use in connection with the power of the stimulation device, . . . the electric energy being in the form of an alternating current through the electric conductors, the intensity of the current through the electric conductors amounting to a predetermined value" Claim 1 has now been amended to clarify that where the current through the conductors decreases, the control device automatically controls the electric source of energy to release more electric energy to restore the predetermined value of current intensity. Independent claim 249 has also been amended to recite these features of the present invention.

For a claim to be anticipated by a reference, each and every element recited in the claim must be present in the reference, either expressly or inherently. Here, the claimed invention of the present application is not anticipated by Bardy because Bardy does not disclose at least the above-noted features of the present invention recited in independent claims 1 and 249.

As explained by Applicant in the present application, an important problem that the present invention overcomes is where the voltage intensity that is strong enough to

provide the desired stimulation of muscles that directly affect the transportation of the content of a patient's intestines, such as the anal sphincter, fades over time due to increasing electric resistance caused by the formation of fibrosis where the conductors engage the muscles. This problem is solved by the present invention through the use of a controlled electric source of energy, which releases an amount of electric energy in the form of an alternating current through electric conductors, wherein the intensity of the current through the electric conductors amounts to a predetermined value, and which releases more electric energy to restore the desired current intensity where the current through the conductors decreases as a result of decreasing current intensity caused, for example, by the formation of fibrosis where the conductors engage the muscles.

Application, p.3, lns. 7-23. The control device controls the electric source of energy to release energy in the form of an alternating current because Applicant has found that a direct current may cause electrolysis in a muscle, which may injure the muscle.

Application, p.3, lns. 24-28.

Bardy does not anticipate independent claims 1 and 249 because Bardy does not teach current control using a controlled electric source of energy which release electric energy in the form of an alternating current with an intensity amounting to a predetermined value, and which release more electric energy to restore the predetermined value of current intensity when the current decreases.

Rather, Bardy discloses an apparatus and method for treating chronic constipation,

FORSELL
Serial No. 09/893,510

which includes a stimulus generator 10 that is shown in Figure 5 of Bardy. The stimulus generator 10 is located within a housing 9 which may be inserted into an abdominal subcutaneous pocket between a patient's abdominal rectus muscles and skin. Bardy, col. 6, lns. 33-44. The stimulus generator 10 includes a pulse generator 47, a power supply 48, that may include one or more batteries any needed voltage regulating means, an alarm 50, an activator 52, a microprocessor controller 54, and a telemetry means 58. Bardy, col. 9, lns. 5-10. The electrical stimuli used by Bardy in his apparatus and method are provided by the controller 54 and the pulse generator 47, Bardy, col. 11, lns. 46-49, and shown in Figures 6 and 7 of Bardy. The electrical stimuli shown in Figures 6 and 7 are described in columns 11 and 12 of Bardy. Figure 6 shows an electrical stimulus voltage waveform 66, which is described by Bardy as a "monophasic" signal of only one polarity, either positive or negative. Each stimulus 66 is a truncated, exponentially decaying wave forms having a maximum voltage of about 10.5 V, a minimum voltage of about 6.8 V, and a slope of about 65% between the maximum and minimum voltages. Bardy, col. 11, lns. 46-65. Bardy also notes that any particular stimulus may have maximum and minimum voltages that range from about 20 microvolts to about 50 volts. Bardy, col. 12, lns. 18-20.

Figure 7 shows an electrical stimulus voltage waveform 68, which is described by Bardy as a "biphasic" signal, since it comprises two stimuli 70 of opposite polarity. Each stimulus 70 may have characteristics that are the same as, or similar to, those described

with respect to stimuli 66. Bardy, col. 12, lns. 35-46. Figure 7 also shows an electrical stimulus voltage waveform 72, which is described by Bardy as a "multiphasic" signal, since it comprises at least three stimuli 74 of alternating polarity. Again, each stimulus 74 may have characteristics that are the same as, or similar to, those described with respect to stimuli 66. Bardy, col. 12, lns. 47-53.

Thus, clearly Bardy does not anticipate claims 1 and 249 because he does not teach using a controlled electric source of energy that releases electric energy in the form of an alternating current through electric conductors with an intensity amounting to a predetermined value, and that releases more electric energy to restore the predetermined value of current intensity when the current through the conductors decreases, as recited in claims 1 and 249. And because Bardy does not anticipate claims 1 and 249, he also does not anticipate those claims of the present application, which depend, either directly or indirectly, from independent claims 1 and 249.

For a claim to be obvious over a combination of prior art references, there must be some suggestion, motivation or teaching in the prior art that would have led one of ordinary skill in the art to combine the references to produce the claimed invention. *E.g.*, *Ashland Oil, Inc. v. Delta Resins & Refracs.*, 776 F.2d 281, 293 (Fed. Cir. 1985). In his rejection of claims 48, 73, 74, 76-79 and 94 under §103(a) as being obvious over Bardy in view of Rosar, the Examiner contends that Bardy fails to disclose components involved in the telemetry of information, but argues that Rosar teaches an implantable medical device

and modulated signals for relaying information from the medical device to external monitoring systems so as to render the rejected claims obvious to one of ordinary skill in the art. The Examiner's rejection of claims 48, 73, 74, 76-79 and 94 under §103(a) fails for several reasons. First, the Examiner fails to point to any suggestion, motivation or teaching in the prior art that would have led to one of ordinary skill in the art to combine the Bardy and Rosar references, as argued by the Examiner. Secondly, even if the combination of these references were obvious, as argued by the Examiner, Rosar does not disclose a wireless remote control for controlling an internal electric source of energy implantable in a patient, which comprises at least one external signal transmitter or transceiver and at least one internal signal receiver or transceiver implantable in a patient, as recited in the rejected claims. Rather, Rosar is directed to a receiver and filtering circuit that produces a filtered digital information signal corresponding to an analog data signal transmitted by a body implantable medical apparatus. Third, Rosar also does not teach the implantable internal electric source of energy recited in claim 48 or the stimulation device embedded in a silicone material recited in claim 94. Finally, given the deficiencies in the teachings of the Bardy reference discussed above, and the fact that Rosar does not compensate for these deficiencies because he does not disclose a control device which controls an electric source of energy that releases electric energy in the form of an alternating current and that restores desired current intensity when the current decreases, as recited in rejected independent claim 1, it is clear that claims 48, 73, 74, 76-

FORSELL
Serial No. 09/893,510

79 and 94, which depend either directly or indirectly from claim 1, are not obvious over the combination of Bardy and Rosar.

Rejected claims 18, 19, 254 and 255 are also not obvious over Bardy alone because the Examiner has failed to provide concrete factual evidence to support his contention that such claims are not patentable over Bardy. In his rejection of claims 18, 19, 254 and 255 under 35 U.S.C. §103(a) as being unpatentable over Bardy alone, the Examiner acknowledges, and then seeks to compensate for, the deficiencies in Bardy with regard to not teaching the patient orientation sensor and electric conductor hook features recited in such claims by arguing that it would have been obvious to one of ordinary skill in the art to modify Bardy's pressure sensor to include an orientation function and to substitute hooks for Bardy's disclosed sutures and staples. In making these arguments, the Examiner failed to provide any prior art references to support her argument, thereby suggesting, in effect, that such modifications are minor and, thus, obvious to persons of ordinary skill in the art. *See* Office Action, p. 5. However, it is not appropriate for an examiner to use his or her own understanding or experience of what would be basic knowledge when making findings for a patentability determination of a claimed invention. Rather, the examiner must rely on "concrete factual evidence" to support a rejection of a claimed invention. *See In re Zurko*, 258 Fed.3d 1379, 1385-86 (Fed. Cir. 2001). The *Zurko* decision requires an Examiner to provide concrete factual evidence to

support a determination that claims 18, 19, 254 and 255 are not patentable because they are obviousness over the cited prior art.

In *Zurko*, the Examiner rejected the claimed invention under 35 U.S.C. §103, relying on a combination of two prior art references. In sustaining the rejection, the Patent Office Board of Appeals "contended that even if the cited UNIX and FILER 2 references did not disclose a trusted path, 'it is basic knowledge that communication in trusted environments is performed over trusted paths' and, moreover, verifying the trusted command in UNIX over a trusted path is 'nothing more than good common sense.'"

Zurko, 258 F.3d at 1385. On appeal, the Federal Circuit rejected the Board's contentions, holding:

This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support. As an administrative tribunal, the Board clearly has expertise in the subject matter over which it exercises jurisdiction. This expertise may provide sufficient support for conclusions as to peripheral issues. With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

Zurko, 258 F.3d at 1385-86. (Emphasis added). The same is true with respect to the Examiner's rejection of claims 18, 19, 254 and 255 under §103(a) as being obvious over *Bardy*. Thus, it is not proper for the Examiner to rely on assertions of minor

FORSELL
Serial No. 09/893,510

modifications that are obvious, and thus known in the art to support her §103(a) rejection of such claims. A copy of the *Zurko* decision is attached for the Examiner's convenience.

In view of the foregoing, it is now believed that all of the claims remaining in the application, *i.e.*, claims 1, 6-19, 20-34, 48-51, 54, 61-67, 71-83, 93-99, 249, 250, 254 and 255, are now in condition for allowance, which action is earnestly solicited. If any issues remain in this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

NIXON & VANDERHYE P.C.

By: Robert A. Molan
Robert A. Molan
Reg. No. 29,834

RAM:dt

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

Serial No. 09/893,510
Excerpt from Merriam-Webster Medical Dictionary



InteliHealth

Enter A Drug Name		Enter A Search Term	
<input type="text"/>	<input type="button" value="Search"/>	<input type="text"/>	<input type="button" value="Search"/>
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Medical Dictionary

The latest word on medical terms

Main Entry: **cardiac sphincter**

Function: *noun*

: the somewhat thickened muscular ring surrounding the opening between the esophagus and the stomach

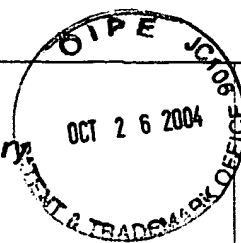
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Serial No. 09/893,510
Interview Summary
June 4, 2004

Interview Summary



Application No.	Applicant(s)	
09/893,510	FORSELL, PETER	
Examiner	Art Unit	
Kamrin R. Landrem	3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) Kamrin R. Landrem. (3) _____

(2) Bob Molan. (4) _____

Date of Interview: June 4th, 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
If Yes, brief description: _____

Claim(s) discussed: Amended independent Claim 1 and original claim 5.

Identification of prior art discussed: _____

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant's representative addressed the incorporation of Claim 5 into independent claim 1. It appears that the Final Rejection (Paper No. 15) was improper. The Examiner will wait for applicant's response to address the withdrawal of finality of the previous office action.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.